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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,056	REIDENBERG ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *3-6,8-11 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 7, 12, 13, 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 01/17/2008, 08/01/2007, 01/04/2007, 04/17/2006, 01/25/2006.

DETAILED ACTION

The receipt is acknowledged of applicants' election filed 12/10/2009, IDS filed 01/17/2008, IDS filed 08/01/2007, IDS filed 01/04/2007, IDS filed 04/17/2006, and IDS filed 01/25/2006.

Claims 1-21 are pending.

Election/Restrictions

1. Applicant's election of Group I, species arthroscopic surgery, claims 1, 2, 7, 12, 13, and 21 in the reply filed on 12/10/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

2. Claims 3-6, 8-11, 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 1, 2, 7, 12, 13, and 21 are included in the prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "transdermal system selected from the group consisting of a topical gel, a lotion, an ointment, a transmucosal system, a transmucosal device, and an iontophoretic delivery system." This is improper Markush format because transdermal system is to be applied to skin and transmucosal system is to be applied to the mucosa, and it is confusing to have the transdermal system selected from transmucosal system or devices.

5. Claim 21 recites the limitation "transdermal system" in 2nd line of the claim. There is insufficient antecedent basis for this limitation in the claim, or in claim 1 from which claim 21 depends because claim 1 recites "transdermal dosage form".

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 7, 12, 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article by Hayes et al. ("A Comparison of pre- and post-surgical administration of bupivacaine or buprenorphine following laparotomy in the rat", currently provided) in view of Reder et al. (US 5,968,547, IDS filed 01/25/2006).

Applicant Claims

Claim 1 is directed to a method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form prior to surgery.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Hayes teaches pre-operative buprenorphine administration reduces the degree of post operative pain (see the entire document specially page 17, left column; page 21, right column; page 22, left column).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Hayes however does not teach buprenorphine was administered in a transdermal dosage form as instantly claimed by claims 1 and 21, time of application of the transdermal dosage from prior to surgery as claimed by claim 2, dose of buprenorphine as claimed by claim 7 and type of surgery as claimed by claim 13.

Reder teaches method for effectively treating pain with buprenorphine to achieve prolonged and effective pain management while at the same time provides the opportunity to reduce side effects, dependence and tolerance which the patients may experience when subjected to prolonged treatment with buprenorphine (abstract; col.3, 1-15, 56-60). The pain management is provided by providing a substantially first order rate of increase of blood plasma concentration of buprenorphine over about three day

time interval using transdermal patch followed by at least two days during which the plasma concentration of buprenorphine is maintained according to the substantially zero order pharmacokinetics by maintaining the same patch in contact with the skin (col.3, lines 21-29; col.4, lines 42-65; col.5, lines 23-34; col.17, lines 52-60). The reference teaches the amount of buprenorphine in the transdermal patch can be at least 5 mg, and adjusted according to the desired delivery rate (col.21, lines 13-34).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to administer buprenorphine pre-operatively to reduce the degree of post-operative pain as taught by Hayes, and use a transdermal patch comprising at least 5 mg of buprenorphine 72 hours before surgery as taught by Reder. One would have been motivated to do so because Reder teaches that such transdermal patches achieve prolonged and effective pain management while at the same time provides the opportunity to reduce side effects, dependence and tolerance which the patients may experience when subjected to prolonged treatment with buprenorphine. One having ordinary skill in the art would apply the patch 72 hours prior to surgery because Reder teaches that the patches provide a substantially first order rate of increase of blood plasma concentration of buprenorphine over about 72 hour time interval using transdermal patch followed by at least two days during which the plasma concentration of buprenorphine is maintained according to the substantially zero order

pharmacokinetics by maintaining the same patch in contact with the skin. One would reasonably expect treating post operative pain by administering transdermal patch comprising at least 5 mg buprenorphine 72 hours prior to surgery wherein the post operative pain is reduced and managed with no side effects or tolerance development.

Regarding the claimed specific surgery as claimed by claim 13, the claimed arthroscopic surgery is a minor short surgery that can be covered by the period of action of the patch taught by the combination of Hayes and Reder. Applicants failed to show unexpected result in using the claimed method for arthroscopic surgery in particular. Therefore, a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

10. Claims 1, 2, 7, 12, 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article by Criado et al. ("Reduction of isoflurane MAC with buprenorphine and morphine in rats", IDS 04/17/2006) in view of Reder et al.

Applicant Claims

Claim 1 is directed to a method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form prior to surgery.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Criado teaches pre-operative analgesia is being increasingly used to provide analgesia in the intraoperative and postoperative period. Buprenorphine was used in 10, 30 and 100 μg/kg (summery on page 252). Criado teaches that buprenorphine has several advantages over morphine such as unremarkable respiratory depression and prolonged duration of analgesia that may extends over the post-operative periods (page 258, left column).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Criado however does not teach buprenorphine was administered in a transdermal dosage form as instantly claimed by claims 1 and 21, time of application of the transdermal dosage from prior to surgery as claimed by claim 2, dose of buprenorphine as claimed by claim 7 and type of surgery as claimed by claim 13.

Transdermal patches to deliver buprenorphine for prolonged periods were taught by Reder as previously discussed in this office action.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to administer buprenorphine pre-operatively to provide post-operative analgesia as taught by Criado, and use a transdermal patch comprising at least 5 mg of buprenorphine 72 hours before surgery as taught by Reder. One would have been motivated to do so because Reder teaches that such transdermal patches achieve prolonged and effective pain management while at the same time provides the opportunity to reduce side effects, dependence and tolerance which the patients may experience when subjected to prolonged treatment with buprenorphine. One having ordinary skill in the art would apply the patch 72 hours prior to surgery because Reder teaches that the patches provide a substantially first order rate of increase of blood plasma concentration of buprenorphine over about 72 hour time interval using transdermal patch followed by at least two days during which the plasma concentration of buprenorphine is maintained according to the substantially zero order pharmacokinetics by maintaining the same patch in contact with the skin. One would reasonably expect treating post operative pain by administering transdermal patch comprising at least 5 mg buprenorphine 72 hours prior to surgery wherein the post operative pain is reduced and managed with no side effects or tolerance development.

Regarding the claimed specific surgery as claimed by claim 13, the claimed arthroscopic surgery is a minor short surgery that can be covered by the period of action of the patch taught by the combination of Criado and Reder. Applicants failed to show unexpected result in using the claimed method for arthroscopic surgery in particular. Therefore, a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

11. Claims 1, 2, 7, 12, 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article by Juhlin-Dannfelt et al. ("Premedication with sublingual buprenorphine for out-patient arthroscopy: reduced need for postoperative pethidine but higher incidence of nausea", IDS 04/17/2006) in view of Reder et al.

Applicant Claims

Claim 1 is directed to a method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form prior to surgery.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Juhlin-Dannfelt teaches pre-operative buprenorphine administration reduces the post operative pain after arthroscopy to enable early and safe discharge after out-patient surgery (see the entire document specially page 634, abstract, left column).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Juhlin-Dannfelt however does not teach buprenorphine was administered in a transdermal dosage form as instantly claimed by claims 1 and 21, time of application of the transdermal dosage from prior to surgery as claimed by claim 2, dose of buprenorphine as claimed by claim 7.

Transdermal patches to deliver buprenorphine for prolonged periods were taught by Reder as previously discussed in this office action.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to administer buprenorphine pre-operatively to reduce the of post-operative pain as taught by Juhlin-Dannfelt, and use a transdermal patch comprising at least 5 mg of buprenorphine 72 hours before surgery as taught by Reder. One would have been motivated to do so because Reder teaches that such transdermal patches achieve prolonged and effective pain management while at the same time provides the opportunity to reduce side effects, dependence and tolerance which the patients may experience when subjected to prolonged treatment with buprenorphine. One having ordinary skill in the art would apply the patch 72 hours prior to surgery because Reder teaches that the patches provide a substantially first order rate of increase of blood plasma concentration of buprenorphine over about 72 hour time interval using transdermal patch followed by at least two days during which the plasma concentration

of buprenorphine is maintained according to the substantially zero order pharmacokinetics by maintaining the same patch in contact with the skin. One would reasonably expect treating post operative pain by administering transdermal patch comprising at least 5 mg buprenorphine 72 hours prior to surgery wherein the post operative pain is reduced and managed with no side effects or tolerance development.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hayes with Reder or over the combination of Criado with Reder and further each combination in view of Juhlin-Dannfelt.

Applicant Claims

Claim 13 is directed to arthroscopic surgery.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combination of Hayes with Reder and the combination of Criado with Reder as discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

The combination of references does not explicitly teach arthroscopic surgery. Juhlin-Dannfelt however teaches arthroscopic surgery.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to treat post operative pain by administering transdermal patch comprising at least 5 mg buprenorphine 72 hours prior to surgery wherein the post operative pain is reduced and managed with no side effects or tolerance development as taught by the combination of Hayes with Reder or the combination of Criado with Reder, and use the method to treat post surgical arthroscopy as taught by Juhlin-Dannfelt. One would have been motivated to do so because Juhlin-Dannfelt teaches that such pre-operative treatment of post-operative pain enables early and safe discharge of patients after out-patients surgery such as arthroscopy. One would reasonably expect treating post operative pain after arthroscopy by administering transdermal patch comprising at least 5 mg buprenorphine 72 hours prior to surgery wherein the post operative pain is reduced and managed with no side effects and patients are early and safely discharged after arthroscopy.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611